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ATTORNEYS FOR PLAINTIFFS PAR PHARMACEUTICAL, INC.,
PAR STERILE PRODUCTS, LLC, AND ENDO PAR INNOVATION COMPANY, LLC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC Plaintiffs, v. SANDOZ INC. Defendant.	Civil Action No. 3:18-cv-14895(BRM)(DEA)

FIRST AMENDED COMPLAINT

Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively "Par"), for their complaint against Sandoz Inc. ("Sandoz"), hereby allege as follows:

PARTIES

1. Plaintiff Par Pharmaceutical, Inc. ("Par Pharmaceutical") is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Pharmaceutical develops, manufactures, and markets pharmaceutical products in the United States.

2. Plaintiff Par Sterile Products, LLC ("Par Sterile Products") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Sterile Products develops, manufactures, and markets injectable pharmaceutical products, and provides manufacturing services to the biopharmaceutical and pharmaceutical industry.

3. Plaintiff Endo Par Innovation Company ("EPIC") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

4. Upon information and belief, Defendant Sandoz Inc. ("Sandoz") is a corporation organized and existing under the law of Colorado, having its corporate offices and principal place of business at 100 College Road West, Princeton, New Jersey 08540. Sandoz is a pharmaceutical company that markets pharmaceutical products in the United States.

NATURE OF ACTION

5. This is an action for infringement of United States Patent Nos. 9,375,478 ("the '478 Patent"), 9,687,526 ("the '526 Patent"), 9,744,209 ("the '209 Patent"), 9,744,239 ("the '239 Patent"), 9,750,785 ("the '785 Patent"), and 9,937,223 ("the '223 Patent") (collectively, "the Patents-in-Suit"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) (patent infringement).

7. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) because, *inter alia*, Sandoz has its principal place of business in New Jersey and maintains laboratories and facilities in New Jersey, and thus resides in this district.

8. This Court has personal jurisdiction over Sandoz because, *inter alia*, Sandoz has its principal place of business in New Jersey and maintains laboratories and facilities in New Jersey, and thus resides in this district.

THE DRUG APPROVAL PROCESS

9. A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from the U.S. Food and Drug Administration ("FDA"), typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a). The sponsor of the NDA is required to submit to FDA information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, and FDA then lists the patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(1) and (c)(2).

10. Alternatively, a company seeking to market a generic version of a previously approved drug is not required to submit a full NDA. Instead, it may file an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j). The generic drug approval process is considered "abbreviated" because the generic manufacturer may piggyback on the innovator company's data and FDA's prior finding of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the previously approved drug (the "referenced listed drug" or "branded drug").

11. In conjunction with this "abbreviated" application process, Congress has put in place a process for resolving patent disputes relating to generic drugs, pursuant to which

an ANDA filer must provide certifications addressing each of the patents listed in the Orange Book for the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12). An ANDA filer may certify, for instance, that it believes a patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *See also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4). This is known as a "Paragraph IV Certification."

12. The filer of an ANDA with a Paragraph IV Certification must also provide notice to both the owner of the listed patents and the holder of the NDA for the referenced listed drug. This "Paragraph IV Notice" must include a detailed statement of the factual and legal bases for the applicant's belief that the challenged patent is invalid or not infringed by the proposed generic product. *See* 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95.

13. If the patentee or NDA holder files a patent infringement action within 45 days of receiving a Paragraph IV Notice from an ANDA filer, final approval of the ANDA is subject to a 30-month stay. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3). The 30-month stay is important to the innovator companies because it protects them from the severe financial harm that could otherwise ensue from the FDA granting approval to an infringing product without first providing an opportunity for the infringement case to be resolved. Put another way, the innovator company is assured of a 30-month period during which it may try to enforce its intellectual property rights and resolve any patent dispute before the generic product enters the market. *See* 21 U.S.C. 355(j)(5)(B)(iii).

FACTUAL BACKGROUND

The Patents-in-Suit

14. On June 28, 2016, the United States Patent and Trademark Office ("PTO") duly and legally issued the '478 Patent, entitled "Vasopressin Formulations for Use in Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '478 Patent is attached as Exhibit A. Par Pharmaceutical owns the '478 Patent.

15. On June 27, 2017, the PTO duly and legally issued the '526 Patent, entitled "Vasopressin Formulations for Use in Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '526 Patent is attached as Exhibit B. Par Pharmaceutical owns the '526 Patent.

16. On August 29, 2017, the PTO duly and legally issued the '209 Patent, entitled "Vasopressin Formulations for Use in Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '209 Patent is attached as Exhibit C. Par Pharmaceutical owns the '209 Patent.

17. On August 29, 2017, the PTO duly and legally issued the '239 Patent, entitled "Vasopressin Formulations for Use in Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '239 Patent is attached as Exhibit D. Par Pharmaceutical owns the '239 Patent.

18. On September 5, 2017, the PTO duly and legally issued the '785 Patent, entitled "Vasopressin Formulations for Use in Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '785 Patent is attached as Exhibit E. Par Pharmaceutical owns the '785 Patent.

19. On April 10, 2018, the PTO duly and legally issued the '223 Patent, entitled "Vasopressin Formulations for Use in Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '223 Patent is attached as Exhibit F. Par Pharmaceutical owns the '223 Patent.

20. EPIC is the exclusive licensee of the Patents-in-Suit.

VASOSTRICT®

21. Vasopressin, the active ingredient in VASOSTRICT® (described below), is a polypeptide hormone that causes contraction of vascular and other smooth muscle cells. VASOSTRICT® is a lifesaving drug often used when the blood pressure of a critical care patient drops precipitously.

22. On September 25, 2012, JHP Pharmaceuticals ("JHP") submitted NDA No. 204485, under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), seeking FDA approval for a vasopressin injection product to increase blood pressure in adults with vasodilatory shock. On April 17, 2014, the FDA approved NDA 204485 as the first FDA-approved vasopressin injection product for use in a clinical setting in the United States.

23. On February 20, 2014, Par Pharmaceutical Companies, Inc. acquired JHP Pharmaceuticals, LLC. On February 26, 2014, JHP Pharmaceuticals, LLC changed its name to Par Sterile Products, LLC.

24. Par Sterile Products submitted supplemental NDAs including supplemental NDA Nos. 204485/S-003 and 204485/S-004 for the current formulations of VASOSTRICT®—20 units/mL in 1mL vials and 200 units/10mL in 10mL multi-dose vials. On March 18, 2016, the FDA approved NDA No. 204485/S-003 for the 20 units/mL in 1mL vial

formulation of VASOSTRICT®. On December 17, 2016, the FDA approved NDA No. 204485/S-004 for the 200 units/10mL in 10mL vial formulation of VASOSTRICT®.

25. Par Sterile Products is the holder of NDA 204485, including all supplements thereto, for VASOSTRICT®.

26. Par timely submitted information regarding the Patents-in-Suit for listing in the Orange Book with respect to VASOSTRICT®, pursuant to 21 U.S.C. § 355(b)(1) and (c)(2). The FDA thereafter listed the Patents-in-Suit in the Orange Book, pursuant to 21 C.F.R. § 314.53(e).

27. VASOSTRICT® is FDA-approved as indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. Par markets and sells its VASOSTRICT® products to hospitals, both directly and via group purchasing organizations and wholesalers. VASOSTRICT® has enjoyed tremendous commercial success, with 2017 annual sales of $400 million.

Sandoz's Infringing Generic Vasopressin Injection Product

28. Upon information and belief, on or before August 31, 2018, Sandoz submitted ANDA No. 212069 ("Sandoz Multi-Dose ANDA") pursuant to 35 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of a proposed generic "Vasopressin Injection USP, 200 units/10mL (20 units/mL) multiple-dose vials," referencing Par's VASOSTRICT® products as the reference listed drug ("Proposed Multi-Dose Vial Product"). The dosage form of the Proposed Multi-Dose Vial Product is a multiple dose injection solution.

29. On or about August 31, 2018, Sandoz sent Par Pharmaceutical, Par Sterile Products, and EPIC a notice stating that Sandoz had submitted the Sandoz Multi-Dose ANDA seeking approval to manufacture, use, or sell the Proposed Multi-Dose Vial Product prior to the expiration of the Patents-in-Suit (the "Multi-Dose Paragraph IV Notice").

30. The Multi-Dose Paragraph IV Notice advised that the Sandoz Multi-Dose ANDA includes Paragraph IV Certifications stating that it is Sandoz's opinion that the Patents-in-Suit are invalid and not infringed by the Proposed Multi-Dose Vial Product.

31. Upon information and belief, on or before October 17, 2018, Sandoz submitted ANDA No. 212068 ("Sandoz Single-Dose ANDA") pursuant to 35 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of a proposed generic "Vasopressin Injection USP, 20 units/1mL, Single-Dose Vials," referencing Par's VASOSTRICT® products as the reference listed drug (the "Proposed Single-Dose Vial Product"). The dosage form of the Proposed Single-Dose Vial Product is a single dose injection solution.

32. On or about October 17, 2018, Sandoz sent Par Pharmaceutical, Par Sterile Products, and EPIC a notice stating that Sandoz had submitted the Sandoz Single-Dose ANDA seeking approval to manufacture, use, or sell the Proposed Single-Dose Vial Product prior to the expiration of the Patents-in-Suit (the "Single-Dose Paragraph IV Notice").

33. The Single-Dose Paragraph IV Notice advised that the Sandoz Single-Dose ANDA includes Paragraph IV Certifications stating that it is Sandoz's opinion that the Patents-in-Suit are invalid and not infringed by the Proposed Single-Dose Vial Product.

COUNT I
INFRINGEMENT OF THE '239 PATENT (SANDOZ ANDA 212069)

34. Par incorporates each of the preceding paragraphs as if fully set forth herein.

35. Sandoz's submission of the Sandoz Multi-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Multi-Dose Vial Product prior to the expiration of the '239 Patent, constitutes infringement of the '239 Patent under 35 U.S.C. § 271(e)(2)(A).

36. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product before expiration of the '239 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '239 Patent under 35 U.S.C. §§ 271(a)-(c).

37. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product would lead to such infringement of at least claim 1 of the '239 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
> a) providing a pharmaceutical composition for intravenous administration consisting of, in a unit dosage form:
> i) from about 0.01mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
> ii) optionally chlorobutanol;
> iii) acetic acid, acetate, or a combination thereof;
> iv) 0-2% vasopressin degradation products; and
> v) water;
> b) diluting the unit dosage form in a diluent to provide a concentration from about 0.1 units/mL to about 1 unit/mL of vasopressin or the pharmaceutically-acceptable salt thereof; and

c) administering the diluted unit dosage form to the human by intravenous administration; wherein:

the unit dosage form has a pH of 3.5 to 4.1;

the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and

the human is hypotensive.

38. If the Proposed Multi-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

39. Any launch by Sandoz of its Proposed Multi-Dose Vial Product before expiration of the '239 Patent would cause Par to suffer immediate and irreparable harm.

40. Upon information and belief, Sandoz was aware of the existence of the '239 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product will lead to infringement of the '239 Patent.

41. Sandoz's infringement of the '239 Patent is willful.

COUNT II
INFRINGEMENT OF THE '223 PATENT (SANDOZ ANDA 212069)

42. Par incorporates each of the preceding paragraphs as if fully set forth herein.

43. Sandoz's submission of the Sandoz Multi-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Multi-Dose Vial Product prior to the expiration of the '223 Patent, constitutes infringement of the '223 Patent under 35 U.S.C. § 271(e)(2)(A).

44. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product before expiration of the '223 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '223 Patent under 35 U.S.C. §§ 271(a)-(c).

45. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product would lead to such infringement of at least claim 1 of the '223 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
> a) providing a pharmaceutical composition for intravenous administration comprising:
> i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof;
> ii) acetate buffer; and
> iii) water; wherein the pharmaceutical composition has a pH from about 3.7 to about 3.8;
> wherein the pharmaceutical composition is provided in a container;
> b) puncturing a dispensing region of the container a first time and drawing from the container a portion of the pharmaceutical composition;
> c) intravenously administering the portion of the pharmaceutical composition to the human; wherein:
> the human is hypotensive;
> d) puncturing the dispensing region of the container a second time and drawing from the container a second portion of the pharmaceutical composition; wherein:
> the second time that the dispensing region of the container is punctured occurs at least 48 hours after the first time that the dispensing region of the container is punctured;
> e) intravenously administering the second portion of the pharmaceutical composition to the human; wherein:
> the administration of the second portion of the pharmaceutical composition provides to the human from about 0.01 units of vasopressin or the pharmaceutically acceptable salt thereof per minute to about 0.1 unites of vasopressin or the pharmaceutically acceptable salt thereof per minute.

46. If the Proposed Multi-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the

method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

47. Any launch by Sandoz of its Proposed Multi-Dose Vial Product before expiration of the '223 Patent would cause Par to suffer immediate and irreparable harm.

48. Upon information and belief, Sandoz was aware of the existence of the '223 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product will lead to infringement of the '223 Patent.

49. Sandoz's infringement of the '223 Patent is willful.

COUNT III
INFRINGEMENT OF THE '478 PATENT (SANDOZ ANDA 212069)

50. Par incorporates each of the preceding paragraphs as if fully set forth herein.

51. Sandoz's submission of the Sandoz Multi-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Multi-Dose Vial Product prior to the expiration of the '478 Patent, constitutes infringement of the '478 Patent under 35 U.S.C. § 271(e)(2)(A).

52. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product before expiration of the '478 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '478 Patent under 35 U.S.C. §§ 271(a)-(c).

53. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial

Product would lead to such infringement of at least claim 1 of the '478 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human in a unit dosage form, wherein the unit dosage form consists essentially of:
> a) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
> b) 10 mM acetate buffer; and
> c) water; wherein:
> the unit dosage form has a pH of 3.8;
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and
> the human is hypotensive

54. If the Proposed Multi-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

55. Any launch by Sandoz of its Proposed Multi-Dose Vial Product before expiration of the '478 Patent would cause Par to suffer immediate and irreparable harm.

56. Upon information and belief, Sandoz was aware of the existence of the '478 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product will lead to infringement of the '478 Patent.

57. Sandoz's infringement of the '478 Patent is willful.

COUNT IV
INFRINGEMENT OF THE '526 PATENT (SANDOZ ANDA 212069)

58. Par incorporates each of the preceding paragraphs as if fully set forth herein.

59. Sandoz's submission of the Sandoz Multi-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Multi-Dose Vial Product prior to the expiration of the '526 Patent, constitutes infringement of the '526 Patent under 35 U.S.C. § 271(e)(2)(A).

60. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product before expiration of the '526 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '526 Patent under 35 U.S.C. §§ 271(a)-(c).

61. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product would lead to such infringement of at least claim 1 of the '526 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
> a) providing a pharmaceutical composition for intravenous administration comprising:
> i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
> ii) acetic acid; and
> iii) water; wherein:
> the pharmaceutical composition has a pH of 3.8;
> b) storing the pharmaceutical composition at 2-8° C. for at least 4 weeks; and
> c) intravenously administering the pharmaceutical composition to the human; wherein:
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; wherein:
> the human is hypotensive; wherein:
> the pharmaceutical composition exhibits less than about 5% degradation after storage at 2-8° C. for about four weeks.

62. If the Proposed Multi-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

63. Any launch by Sandoz of its Proposed Multi-Dose Vial Product before expiration of the '526 Patent would cause Par to suffer immediate and irreparable harm.

64. Upon information and belief, Sandoz was aware of the existence of the '526 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product will lead to infringement of the '526 Patent.

65. Sandoz's infringement of the '526 Patent is willful.

COUNT V
INFRINGEMENT OF THE '785 PATENT (SANDOZ ANDA 212069)

66. Par incorporates each of the preceding paragraphs as if fully set forth herein.

67. Sandoz's submission of the Sandoz Multi-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Multi-Dose Vial Product prior to the expiration of the '785 Patent, constitutes infringement of the '785 Patent under 35 U.S.C. § 271(e)(2)(A).

68. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product before expiration of the '785 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '785 Patent under 35 U.S.C. §§ 271(a)-(c).

69. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product would lead to such infringement of at least claim 1 of the '785 Patent, which recites as follows:

> Claim 1: A pharmaceutical composition comprising, in a unit dosage form, from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof, wherein the unit dosage form further comprises impurities that are present in an amount of 0.9% to 1.7%; wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1, and wherein the unit dosage form has a pH of 3.7-3.9.

70. If the Proposed Multi-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

71. Any launch by Sandoz of its Proposed Multi-Dose Vial Product before expiration of the '785 Patent would cause Par to suffer immediate and irreparable harm.

72. Upon information and belief, Sandoz was aware of the existence of the '785 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product will lead to infringement of the '785 Patent.

73. Sandoz's infringement of the '785 Patent is willful.

COUNT VI
INFRINGEMENT OF THE '209 PATENT (SANDOZ ANDA 212069)

74. Par incorporates each of the preceding paragraphs as if fully set forth herein.

75. Sandoz's submission of the Sandoz Multi-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage

in the commercial manufacture, use, and sale of its Proposed Multi-Dose Vial Product prior to the expiration of the '209 Patent, constitutes infringement of the '209 Patent under 35 U.S.C. § 271(e)(2)(A).

76. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product before expiration of the '209 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '209 Patent under 35 U.S.C. §§ 271(a)-(c).

77. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product would lead to such infringement of at least claim 1 of the '209 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human a unit dosage form, wherein the unit dosage form comprises from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof; wherein:
>
> the unit dosage form has a pH of 3.7-3.9;
>
> the unit dosage form further comprises impurities that are present in an amount of 0.9% - 1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1;
>
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and
>
> the human is hypotensive

78. If the Proposed Multi-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

79. Any launch by Sandoz of its Proposed Multi-Dose Vial Product before expiration of the '209 Patent would cause Par to suffer immediate and irreparable harm.

80. Upon information and belief, Sandoz was aware of the existence of the '209 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product will lead to infringement of the '209 Patent.

81. Sandoz's infringement of the '209 Patent is willful.

COUNT VII
INFRINGEMENT OF THE '239 PATENT (SANDOZ ANDA 212068)

82. Par incorporates each of the preceding paragraphs as if fully set forth herein.

83. Sandoz's submission of the Sandoz Single-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Single-Dose Vial Product prior to the expiration of the '239 Patent, constitutes infringement of the '239 Patent under 35 U.S.C. § 271(e)(2)(A).

84. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product before expiration of the '239 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '239 Patent under 35 U.S.C. §§ 271(a)-(c).

85. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product would lead to such infringement of at least claim 1 of the '239 Patent, which recites as follows:

Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:

a) providing a pharmaceutical composition for intravenous administration consisting of, in a unit dosage form:

i) from about 0.01mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;

ii) optionally chlorobutanol;

iii) acetic acid, acetate, or a combination thereof;

iv) 0-2% vasopressin degradation products; and

v) water;

b) diluting the unit dosage form in a diluent to provide a concentration from about 0.1 units/mL to about 1 unit/mL of vasopressin or the pharmaceutically-acceptable salt thereof; and

c) administering the diluted unit dosage form to the human by intravenous administration; wherein:

the unit dosage form has a pH of 3.5 to 4.1;

the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and

the human is hypotensive.

86. If the Proposed Single-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

87. Any launch by Sandoz of its Proposed Single-Dose Vial Product before expiration of the '239 Patent would cause Par to suffer immediate and irreparable harm.

88. Upon information and belief, Sandoz was aware of the existence of the '239 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product will lead to infringement of the '239 Patent.

89. Sandoz's infringement of the '239 Patent is willful.

COUNT VIII
INFRINGEMENT OF THE '223 PATENT (SANDOZ ANDA 212068)

90. Par incorporates each of the preceding paragraphs as if fully set forth herein.

91. Sandoz's submission of the Sandoz Single-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Single-Dose Vial Product prior to the expiration of the '223 Patent, constitutes infringement of the '223 Patent under 35 U.S.C. § 271(e)(2)(A).

92. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product before expiration of the '223 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '223 Patent under 35 U.S.C. §§ 271(a)-(c).

93. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product would lead to such infringement of at least claim 1 of the '223 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
> a) providing a pharmaceutical composition for intravenous administration comprising:
> i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof;
> ii) acetate buffer; and
> iii) water; wherein the pharmaceutical composition has a pH from about 3.7 to about 3.8;
> wherein the pharmaceutical composition is provided in a container;
> b) puncturing a dispensing region of the container a first time and drawing from the container a portion of the pharmaceutical composition;

c) intravenously administering the portion of the pharmaceutical composition to the human; wherein:

the human is hypotensive;

d) puncturing the dispensing region of the container a second time and drawing from the container a second portion of the pharmaceutical composition; wherein:

the second time that the dispensing region of the container is punctured occurs at least 48 hours after the first time that the dispensing region of the container is punctured;

e) intravenously administering the second portion of the pharmaceutical composition to the human; wherein:

the administration of the second portion of the pharmaceutical composition provides to the human from about 0.01 units of vasopressin or the pharmaceutically acceptable salt thereof per minute to about 0.1 unites of vasopressin or the pharmaceutically acceptable salt thereof per minute.

94. If the Proposed Single-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

95. Any launch by Sandoz of its Proposed Single-Dose Vial Product before expiration of the '223 Patent would cause Par to suffer immediate and irreparable harm.

96. Upon information and belief, Sandoz was aware of the existence of the '223 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product will lead to infringement of the '223 Patent.

97. Sandoz's infringement of the '223 Patent is willful.

COUNT IX
INFRINGEMENT OF THE '478 PATENT (SANDOZ ANDA 212068)

98. Par incorporates each of the preceding paragraphs as if fully set forth herein.

99. Sandoz's submission of the Sandoz Single-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Single-Dose Vial Product prior to the expiration of the '478 Patent, constitutes infringement of the '478 Patent under 35 U.S.C. § 271(e)(2)(A).

100. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product before expiration of the '478 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '478 Patent under 35 U.S.C. §§ 271(a)-(c).

101. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product would lead to such infringement of at least claim 1 of the '478 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human in a unit dosage form, wherein the unit dosage form consists essentially of:
>
> a) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
>
> b) 10 mM acetate buffer; and
>
> c) water; wherein:
>
> the unit dosage form has a pH of 3.8;
>
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and
>
> the human is hypotensive

102. If the Proposed Single-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the

method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

103. Any launch by Sandoz of its Proposed Single-Dose Vial Product before expiration of the '478 Patent would cause Par to suffer immediate and irreparable harm.

104. Upon information and belief, Sandoz was aware of the existence of the '478 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product will lead to infringement of the '478 Patent.

105. Sandoz's infringement of the '478 Patent is willful.

COUNT X
INFRINGEMENT OF THE '526 PATENT (SANDOZ ANDA 212068)

106. Par incorporates each of the preceding paragraphs as if fully set forth herein.

107. Sandoz's submission of the Sandoz Single-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Single-Dose Vial Product prior to the expiration of the '526 Patent, constitutes infringement of the '526 Patent under 35 U.S.C. § 271(e)(2)(A).

108. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product before expiration of the '526 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '526 Patent under 35 U.S.C. §§ 271(a)-(c).

109. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial

Product would lead to such infringement of at least claim 1 of the '526 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
> a) providing a pharmaceutical composition for intravenous administration comprising:
> i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
> ii) acetic acid; and
> iii) water; wherein:
> the pharmaceutical composition has a pH of 3.8;
> b) storing the pharmaceutical composition at 2-8° C. for at least 4 weeks; and
> c) intravenously administering the pharmaceutical composition to the human; wherein:
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; wherein:
> the human is hypotensive; wherein:
> the pharmaceutical composition exhibits less than about 5% degradation after storage at 2-8° C. for about four weeks.

110. If the Proposed Single-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

111. Any launch by Sandoz of its Proposed Single-Dose Vial Product before expiration of the '526 Patent would cause Par to suffer immediate and irreparable harm.

112. Upon information and belief, Sandoz was aware of the existence of the '526 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product will lead to infringement of the '526 Patent.

113. Sandoz's infringement of the '526 Patent is willful.

COUNT XI
INFRINGEMENT OF THE '785 PATENT (SANDOZ ANDA 212068)

114. Par incorporates each of the preceding paragraphs as if fully set forth herein.

115. Sandoz's submission of the Sandoz Single-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Single-Dose Vial Product prior to the expiration of the '785 Patent, constitutes infringement of the '785 Patent under 35 U.S.C. § 271(e)(2)(A).

116. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product before expiration of the '785 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '785 Patent under 35 U.S.C. §§ 271(a)-(c).

117. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product would lead to such infringement of at least claim 1 of the '785 Patent, which recites as follows:

> Claim 1: A pharmaceutical composition comprising, in a unit dosage form, from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof, wherein the unit dosage form further comprises impurities that are present in an amount of 0.9% to 1.7%; wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1, and wherein the unit dosage form has a pH of 3.7-3.9.

118. If the Proposed Single-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

119. Any launch by Sandoz of its Proposed Single-Dose Vial Product before expiration of the '785 Patent would cause Par to suffer immediate and irreparable harm.

120. Upon information and belief, Sandoz was aware of the existence of the '785 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product will lead to infringement of the '785 Patent.

121. Sandoz's infringement of the '785 Patent is willful.

COUNT XII
INFRINGEMENT OF THE '209 PATENT (SANDOZ ANDA 212068)

122. Par incorporates each of the preceding paragraphs as if fully set forth herein.

123. Sandoz's submission of Sandoz Single-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Single-Dose Vial Product prior to the expiration of the '209 Patent, constitutes infringement of the '209 Patent under 35 U.S.C. § 271(e)(2)(A).

124. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product before expiration of the '209 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '209 Patent under 35 U.S.C. §§ 271(a)-(c).

125. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product would lead to such infringement of at least claim 1 of the '209 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human a unit dosage form, wherein the unit dosage form comprises from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof; wherein:
>
> the unit dosage form has a pH of 3.7-3.9;
>
> the unit dosage form further comprises impurities that are present in an amount of 0.9% - 1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1;
>
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and
>
> the human is hypotensive

126. If the Proposed Single-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

127. Any launch by Sandoz of its Proposed Single-Dose Vial Product before expiration of the '209 Patent would cause Par to suffer immediate and irreparable harm.

128. Upon information and belief, Sandoz was aware of the existence of the '209 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product will lead to infringement of the '209 Patent.

129. Sandoz's infringement of the '209 Patent is willful.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Sandoz has infringed the '239 Patent, and a declaration that Sandoz's commercial manufacture, distribution, use, and sale of its Proposed Multi-Dose Vial Product would induce infringement of the '239 Patent;

B. A judgment that Sandoz has infringed the '239 Patent, and a declaration that Sandoz's commercial manufacture, distribution, use, and sale of its Proposed Single-Dose Vial Product would induce infringement of the '239 Patent;

C. A judgment that Sandoz has infringed the '223 Patent, and a declaration that Sandoz's commercial manufacture, distribution, use, and sale of its Proposed Multi-Dose Vial Product would induce infringement of the '223 Patent;

D. A judgment that Sandoz has infringed the '223 Patent, and a declaration that Sandoz's commercial manufacture, distribution, use, and sale of its Proposed Single-Dose Vial Product would induce infringement of the '223 Patent;

E. A judgment that Sandoz has infringed the '478 Patent, and a declaration that Sandoz's commercial manufacture, distribution, use, and sale of its Proposed Multi-Dose Vial Product would induce infringement of the '478 Patent;

F. A judgment that Sandoz has infringed the '478 Patent, and a declaration that Sandoz's commercial manufacture, distribution, use, and sale of its Proposed Single-Dose Vial Product would induce infringement of the '478 Patent;

G. A judgment that Sandoz has infringed the '526 Patent, and a declaration that Sandoz's commercial manufacture, distribution, use, and sale of its Proposed Multi-Dose Vial Product would induce infringement of the '526 Patent;

H. A judgment that Sandoz has infringed the '526 Patent, and a declaration that Sandoz's commercial manufacture, distribution, use, and sale of its Proposed Single-Dose Vial Product would induce infringement of the '526 Patent;

I. A judgment that Sandoz has infringed the '785 Patent, and a declaration that Sandoz's commercial manufacture, distribution, use, and sale of its Proposed Multi-Dose Vial Product would induce infringement of the '785 Patent;

J. A judgment that Sandoz has infringed the '785 Patent, and a declaration that Sandoz's commercial manufacture, distribution, use, and sale of its Proposed Single-Dose Vial Product would induce infringement of the '785 Patent;

K. A judgment that Sandoz has infringed the '209 Patent, and a declaration that Sandoz's commercial manufacture, distribution, use, and sale of its Proposed Multi-Dose Vial Product would induce infringement of the '209 Patent;

L. A judgment that Sandoz has infringed the '209 Patent, and a declaration that Sandoz's commercial manufacture, distribution, use, and sale of its Proposed Single-Dose Vial Product would induce infringement of the '209 Patent;

M. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Sandoz's Multi-Dose ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the last expiration date of the Patents-in-Suit, including any extensions;

N. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Sandoz's Single-Dose ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the last expiration date of the Patents-in-Suit, including any extensions;

O. A permanent injunction, pursuant to 35 U.S.C. §271(e)(4)(B) and 35 U.S.C. § 283, restraining and enjoining Sandoz, its officers, agents, servants and employees, and

those persons in active concert or participation with any of them, from infringement of the Patents-in-Suit for the full terms thereof, including any extensions;

P. An order that damages or other monetary relief be awarded to Plaintiffs if Sandoz engages in the commercial manufacture, use, offer to sale, sale, distribution, or importation of Sandoz's Proposed Multi-Dose Vial Product, or induces such conduct by others, prior to the expiration of the Patents-in-Suit, and any additional period of exclusivity to which Plaintiffs are or become entitled, and that such damages or monetary relief be trebled and awarded to Plaintiffs with prejudgment interest;

Q. An order that damages or other monetary relief be awarded to Plaintiffs if Sandoz engages in the commercial manufacture, use, offer to sale, sale, distribution, or importation of Sandoz's Proposed Single-Dose Vial Product, or induces such conduct by others, prior to the expiration of the Patents-in-Suit, and any additional period of exclusivity to which Plaintiffs are or become entitled, and that such damages or monetary relief be trebled and awarded to Plaintiffs with prejudgment interest;

R. Reasonable attorneys' fees, filing fees, and reasonable costs of suit incurred by Plaintiffs in this action; and

S. Such other and further relief as the Court may deem just and proper.

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